EVEREST-I: One-year Optilume™ BPH Catheter System Efficacy and Safety Experience
The Optilume™ BPH Catheter System

• The Optilume™ BPH Catheter System is the first-ever minimal invasive treatment that provides TURP-like results without cutting, burning, steaming or leaving a permanent implant behind.

• The system creates a TransUrethral Anterior commissurotomy of the Prostate (TUAP).

• The distal end of the catheter has a uniquely shaped semi-compliant inflatable balloon that is coated with a proprietary coating containing the active pharmaceutical paclitaxel. The drug coating covers the working length of the balloon body.

• The Optilume BPH System is comprised of a pre-dilation un-coated balloon catheter and a post dilation drug coated balloon (DCB) catheter.
Mechanical Dilation

- Optilume™ BPH Catheter System is used to perform a TransUrethral Anterior commissurotomy of the Prostate (TUAP). The low-pressure dilation alleviates obstructive BPH by opening and expanding the anterior commissure increasing the size of the prostatic urethra.

- Multiple device sizes are available to provide customized treatment based on prostate size

Drug Delivery

- Balloon circumferentially delivers an anti-proliferative drug (Paclitaxel) that maintains the opening of the newly split tissue

Optilume Procedure

- Minimizes or eliminates the common side effects associated with other surgical BPH procedures.
Optilume BPH Catheter Clinical Data

• The Optilume™ BPH Catheter System is currently under investigation in the prospective, randomized, double blinded PINNACLE trial in 20 US sites.

• A pilot study, EVEREST-I, has completed enrollment and the treatment of 80 subjects with BPH at six Latin American investigational sites, two in Panama and four in the Dominican Republic. Subject follow-up is currently ongoing. As of February 10, 2020, 73 subjects had completed the 1-Year follow-up visit and 22 subjects had completed the 2-Year follow-up visit.

• The study is GCP compliant with Steven Kaplan, M.D. Professor of Urology, Icahn School of Medicine at Mount Sinai in NYC is the study Principle Investigator.
IPSS - Plain Balloon vs. Optilume Drug Coated Balloon
EVEREST STUDY RESULTS

- Significant reduction in IPSS and increase in Qmax post-procedure sustained through 1 year.
Improvement in symptoms more pronounced than other MIST therapies\textsuperscript{1,2} and more immediate than TURP\textsuperscript{3,4}.

\textbf{EVEREST IPSS RESULTS}

\begin{itemize}
\item Change in IPSS Over Time by Treatment Type
\end{itemize}

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\textsuperscript{1}Roehrborn CG, Gange SN, Shore ND, et al. \textit{J Urol.} 2013;190:2161-67
\textsuperscript{4}Kumar N, Vasudeva P, Kumar A, Singh H. \textit{LUTS.} 2018;10(1):17-20
Everest Qmax Results

• Improvement in symptoms more pronounced than other MIST therapies\(^1,2\) and more immediate than TURP\(^3,4\).

Symptomatic improvement similar for all balloon sizes.

Largest balloon size achieved maximum symptom relief by 6 months, similar to TURP and Rezum.

Smallest balloon size achieved maximum symptom relief by day 30.
• Largest balloon size showed significant increase in Qmax immediately post procedure, with slight deterioration seen at 1 year.

• Small/Medium balloons showed large increase in Qmax to ~17 mL/sec, sustained through 1 year.

Change in Qmax Over Time by Device Size

- Peak Flow Rate (mL/sec)
- Time (days)

- Small Diameter
- Medium Diameter
- Large Diameter
Optilume BPH Patient 1yr Follow-up Cysto

Everest Patient 505-008

Baseline
Qmax 11 ml/sec
IPSS 15

1yr Follow-up
Qmax 21 ml/sec
IPSS 3

Note: The open anterior split or commissurotomy could not be fully captured in a single cystoscopic image.